Ombudsman's Annual Report for 2008
FDA, Center for Drug Evaluation and Research (CDER)

The CDER Ombudsman's Office houses both the CDER Ombudsman, Virginia L. Behr, and CDER's Product Jurisdiction Officer, LCDR Ayoub Suliman. This report briefly explains their roles and details the number and variety of interactions between the Ombudsman's Office and its constituents.

I. The Ombudsman's Role

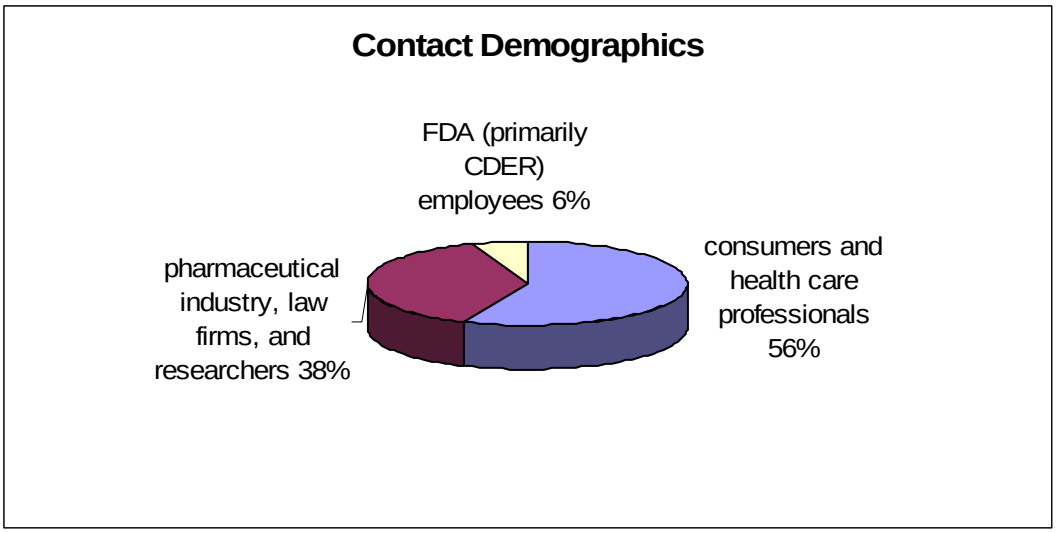
The United States Ombudsman's Association (USOA) defines a governmental Ombudsman as "an independent, impartial public official with authority and responsibility to receive, investigate or informally address complaints about governmental actions, and, when appropriate, make findings and recommendations, and publish reports."

The CDER Ombudsman primarily receives inquiries and investigates complaints from the regulated pharmaceutical industry (or the law firms representing them) and consumers and also provides general information on product development and regulation. If requested, the Ombudsman can informally resolve disputes or disseminate information about established appeals processes and other formal mechanisms for dispute resolution. The Ombudsman also receives comments from inside and outside the Center about the effectiveness of programs and about problems that impede CDER's performance of its mission. The Ombudsman makes recommendations for Center improvement to the Center Director but cannot require action or mandate change because ombudsmen do not have disciplinary or enforcement powers.

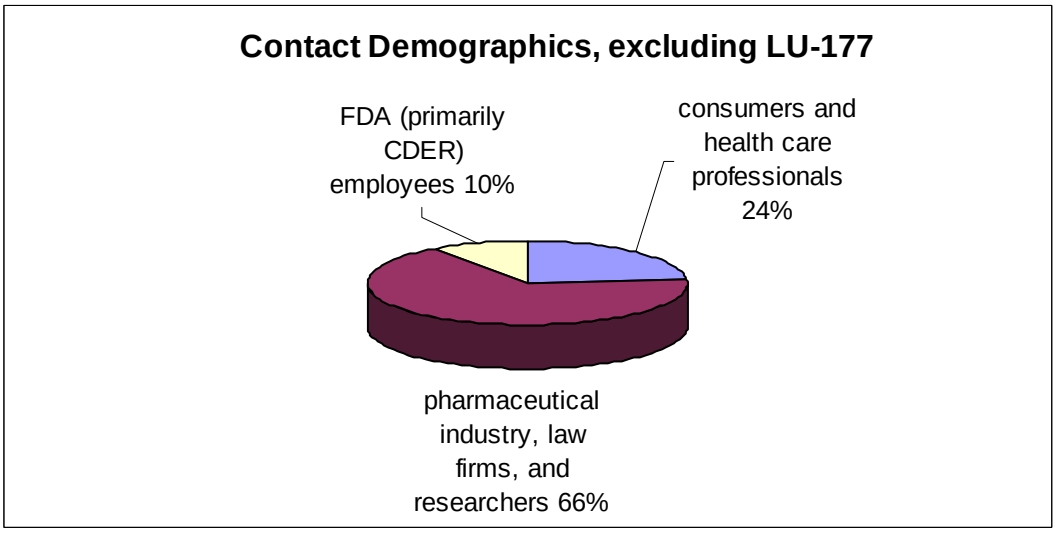
The CDER Ombudsman's Office draws its ethical principles and standards from those established by the Coalition of Federal Ombudsmen, USOA, and the International Ombudsman Association. These include standards for ensuring confidentiality, neutrality, independence, a credible review process, and informality. The Office reports to the Director of the Office of the Chief of Staff within the Office of the Center Director. The Ombudsman is a member of the Coalition of Federal Ombudsmen.

II. Contact Methods, Demographics, and Most Common Topics

Consumers, law firms, and the pharmaceutical industry can contact the Ombudsman by fax, phone, postal mail, and electronic mail. The data presented below encompass the full 2008 calendar year. In total, the Ombudsman received 833 communications, a 26% increase over the previous year. Of the 833 communications, the vast majority (97%) were received via electronic mail and phone. In many instances, several emails or phone calls were exchanged per case; those follow up correspondences were not counted for this report (i.e. the numbers below refer to initial contacts only).



As shown by the graphic above, the largest percentage of contacts came from consumers and health care professionals; this appears to be a change from last year. Upon closer inspection however, 302 of the 469 contacts made by this group were consumer emails asking that CDER allow patient access to the cancer drug LU-177. If the contacts made for that one topic are removed from the analysis, the graphic looks like this:



<u>Number of contacts and demographics</u>

- Phone = 210
  - Consumers and health care professionals = 44
  - Pharmaceutical industry, law firms, consultants, and public or private research institutions = 138
  - CDER employees = 28 (personnel problems, questions about scientific differences of opinion, and general enquiries from ORA staff)
- Email = 601
  - Consumers and health care professionals = 415

    - Pharmaceutical industry, law firms, consultants, and public or private research institutions = 168
    - CDER employees = 18 (personnel problems, questions about scientific differences of opinion, and general enquiries from ORA staff)
- Fax (7) and Postal mail (15) = 22
    - Consumers and health care professionals = 10
    - Pharmaceutical industry, law firms, consultants, and public or private research institutions = 12

Most Common Contact Topics from the Pharmaceutical Industry, Law Firms, Consultants, and Public or Private Research Institutions

- Disagreements over study design
- Questions about off label marketing of drugs
- Inspection delays, especially foreign sites
- Regulatory jurisdiction
- Generic drug decisions (approvability) and taking too long to review applications
- Office of New Drugs (OND) review delays resulting in slowed drug development
- Unresponsiveness and communication delays
- Labeler code assignments and registration listing assignments taking too long
- Whistleblower reporting of unethical clinical research conduct including institutional review board issues and clinical study protocol violations
- Perceived unfair handling of an issue
- Lengthy response times to Citizen Petitions and Suitability Petitions
- Import/Export issues, usually detained products, embargo, or seizures
- Enforcement actions taken on marketed drugs that do not have FDA approval
- Drug shortage problems
- Investigational New Drug Application (IND) and New Drug Application (NDA) requirements; review and application process questions
- Freedom of Information Act requests (response delay) and backlog
- User Fee assessments and Orange Book listings
- Unlawful promotional activities by competitors

Most Common Contact Topics from Consumers and Health Care Professionals

- Reporting of drug adverse events and medication errors
- LU-177 for carcinoid patients
    - Patients asked FDA to approve this product for marketing in the U.S.
    - Constituted 73% of emails from this demographic
- Violative conduct by pharmaceutical companies (off-label promotion and violative manufacturing procedures)
- Drug costs and insurance problems
- Outdated information on FDA website
- Disagree with FDA recommendation for pediatric use of over-the-counter cough/cold products. See http://www.fda.gov/cder/drug/advisory/cough_cold.htm

- Misleading product websites and online pharmacy 'spam' email
    - The highest number of contacts in this category were about the drug Copaxone – multiple sclerosis patients and those who care for them sent alerts stating that the sponsor made unapproved claims on the company's website
- Drug shortages
- Complaints from consumers about their doctors
- The prevalence of unapproved marketed drugs
- Contaminated or adulterated drug suspected
- Generic drug doesn't seem to work the same as the brand drug
- Oxycontin abuse and pleas to remove it from the market
- Albuterol inhalers
    - Because chlorofluorocarbons (CFCs) deplete the ozone layer, patients using CFC propelled albuterol metered dose inhalers are being switched to hydrofluoroalkanes (HFAs) propelled albuterol inhalers. The Ombudsman's Office received several complaints that the HFA inhalers do not deliver the drug dose forcefully enough and get clogged up too easily. For more information, see http://www.fda.gov/cder/mdi/mdifaqs.htm

III. Other Activities

The Ombudsman served as the CDER representative on a FDA level working group to establish an Agency level appeals process for resolving internal scientific disputes.

The Ombudsman and Product Jurisdiction Officer also met with Network Leaders at CDRH in order to improve and promote intercenter communications.

IV. Product Jurisdiction for Combination and Single Entity Products

This year, the Ombudman's Office welcomed LCDR Ayoub Suliman as CDER's Product Jurisdiction Officer. The Product Jurisdiction Officer duties were previously performed by the CDER Ombudsman.

Many proposed products must be regulated by the FDA, but it is often not obvious which Center within FDA should take the lead for product review and regulation, particularly for combination products. The Product Jurisdiction Officer serves as CDER's expert on establishing the regulatory identity of products as drugs, biologics, devices, or a combination of two or more (e.g. biologic and a device combined into one product), specifically to determine which FDA Center is most appropriate for reviewing each product. The Product Jurisdiction Officer responds to all Requests for Designation (RFD) from sponsors via the FDA Office of Combination Products (OCP) under 21 CFR Part 3.7 and to other informal requests for assignment of combination and single entity (noncombination) products.

This calendar year, the CDER's Product Jurisdiction Officer responded to hundreds of informal jurisdiction questions from within and outside FDA and put forth CDER's position on 26 RFDs (OCP received 67 RFDs, 34 of which were not filed. Of the 33 filed, OCP requested CDER consultation for 26 of them), most of which were drug/device combinations. The apparent reduction in RFDs as compared to last year was balanced by an increase in informal enquiries. More information about jurisdictional determinations can be found on the OCP website at http://www.fda.gov/oc/combination/.

IV. Outreach Efforts

The CDER Ombudsman's Office conducted outreach to explain the Ombudsman's functions including product jurisdiction and dispute resolution at several venues; these included presentations to some of the CDER Offices, a Johnson & Johnson Regulatory Education and Development Seminar, an American Health Lawyers Association meeting, and several CDER New Reviewer's Workshops.